

# EC Declaration of Conformity

By the responsible manufacturer:

Translumina® GmbH  
 Neue Rottenburger Str. 50  
 72379 Hechingen  
 Germany



Bertifikat - Certificate - Certificat

Translumina® GmbH declares under its sole responsibility that the below entitled Medical Device complies to the requirements of the Medical Device Directive 93/42/EEC as amended by directive 2007/47/EC of the European Union.

The Quality Management System is in conformity with the requirements and the Conformity Assessment Procedure was followed in accordance to MDD 93/42/EEC, Annex II

The device Yukon® Choice PC Sirolimus Eluting Coronary Stent System in all variations is classified as Class III as per Annexure IX, Rule 8 and Rule 13 of MDD 93/42/EEC of June 14<sup>th</sup> 1993 as amended

The device Yukon® Choice PC Sirolimus Eluting Coronary Stent System has been manufactured as per the following standards:

EN ISO 13485, EN ISO 14971, EN 1707, EN 20594-1, EN ISO 10555-1/4, EN ISO 14630, EN ISO 25539-2, EN ISO 12417-1, ISO 5832-1, EN 62366, EN ISO 14155, EN ISO 10993-1/7, EN 868-5, EN ISO 11607-1/2, EN 1041, EN ISO 15223-1, EN ISO 14644-1 5, EN 656-1, EN ISO 11135

Issue of this certificate

## Yukon® Choice PC Sirolimus Eluting Coronary Stent System

Ref. No.:

YCPC2008	YCPC2208	YCPC2508	YCPC2708	YCPC3008	YCPC3508	YCPC4008
YCPC2012	YCPC2212	YCPC2512	YCPC2712	YCPC3012	YCPC3512	YCPC4012
YCPC2016	YCPC2216	YCPC2516	YCPC2716	YCPC3016	YCPC3516	YCPC4016
YCPC2018	YCPC2218	YCPC2518	YCPC2718	YCPC3018	YCPC3518	YCPC4018
YCPC2021	YCPC2221	YCPC2521	YCPC2721	YCPC3021	YCPC3521	YCPC4021
YCPC2024	YCPC2224	YCPC2524	YCPC2724	YCPC3024	YCPC3524	YCPC4024
YCPC2028	YCPC2228	YCPC2528	YCPC2728	YCPC3028	YCPC3528	YCPC4028
YCPC2032	YCPC2232	YCPC2532	YCPC2732	YCPC3032	YCPC3532	YCPC4032
			YCPC2740	YCPC3040	YCPC3540	YCPC4040

Certificate Registration Number

17 0353 QS/NB  
 (EC Certificate - Full Quality Assurance System)  
 17 0354 CN/NB  
 (EC Design-Examination Certificate)

Notified Body's No.  
 Notified Body

1023  
 ITC Zlín  
 třída Tomáše Bati 299  
 Louky  
 763 02 Zlín  
 Czech Republic  
[www.itczlin.cz](http://www.itczlin.cz)

Validity of this certificate:

**2017-07-31 - 2022-07-30**

Hechingen, 2017-08-02

Eric Kumpa  
 Manager QA/RA

Dr. Boris Behnisch  
 Business Development

[Vers.2014/01]

This document has to be maintained at least five years after the last production of the concerned product was achieved.



# EC Declaration of Conformity

By the responsible manufacturer:

Translumina® GmbH  
Neue Rottenburger Str. 50  
72379 Hechingen  
Germany

**translumina®**

Translumina® GmbH declares under its sole responsibility that the below entitled Medical Device complies to the requirements of the Medical Device Directive 93/42/EEC as amended by directive 2007/47/EC of the European Union

The Quality Management System is in conformity with the requirements and the Conformity Assessment Procedure was followed in accordance to MDD 93/42/EEC, Annex II

The device Yukon® Chrome PC Sirolimus Eluting Coronary Stent System in all variations is classified as Class III as per Annexure IX, Rule 8 and Rule 13 of MDD 93/42/EEC of June 14<sup>th</sup> 1993 as amended.

The device Yukon® Chrome PC Sirolimus Eluting Coronary Stent System has been manufactured as per the following standards:

EN ISO 13485, EN ISO 14971, EN 1707, EN 20594-1, EN ISO 10555-1/4, EN ISO 14630, EN ISO 25539-2, EN ISO 12417-1, ISO 5832-5, EN 62366, EN ISO 14155, EN ISO 10993-1/7, EN 868-5, EN ISO 11607-1/2, EN 1041, EN ISO 15223-1, EN ISO 14644-1 5, EN 556-1, EN ISO 11135

Issue of this certificate

## Yukon® Chrome PC Sirolimus Eluting Coronary Stent System

Ref. No.:

T-CMG2008PC	T-CMG22508PC	T-CMG2508PC	T-CMG27508PC	T-CMG3008PC	T-CMG3508PC	T-CMG4008PC
T-CMG2012PC	T-CMG22512PC	T-CMG2512PC	T-CMG27512PC	T-CMG3012PC	T-CMG3512PC	T-CMG4012PC
T-CMG2016PC	T-CMG22516PC	T-CMG2516PC	T-CMG27516PC	T-CMG3016PC	T-CMG3516PC	T-CMG4016PC
T-CMG2018PC	T-CMG22518PC	T-CMG2518PC	T-CMG27518PC	T-CMG3018PC	T-CMG3518PC	T-CMG4018PC
T-CMG2021PC	T-CMG22521PC	T-CMG2521PC	T-CMG27521PC	T-CMG3021PC	T-CMG3521PC	T-CMG4021PC
T-CMG2024PC	T-CMG22524PC	T-CMG2524PC	T-CMG27524PC	T-CMG3024PC	T-CMG3524PC	T-CMG4024PC
T-CMG2028PC	T-CMG22528PC	T-CMG2528PC	T-CMG27528PC	T-CMG3028PC	T-CMG3528PC	T-CMG4028PC
T-CMG2032PC	T-CMG22532PC	T-CMG2532PC	T-CMG27532PC	T-CMG3032PC	T-CMG3532PC	T-CMG4032PC
			T-CMG27540PC	T-CMG3040PC	T-CMG3540PC	T-CMG4040PC

Certificate Registration Number

17 0353 QS/NB  
(EC Certificate - Full Quality Assurance System)  
17 0355 CN/NB  
(EC Design-Examination Certificate)

Notified Body's No.  
Notified Body

1023  
ITC Zlín  
třída Tomáše Bati 299  
Louky  
763 02 Zlín  
Czech Republic  
[www.itczlin.cz](http://www.itczlin.cz)

Validity of this certificate:

2017-07-31 - 2022-07-30

Hechingen, 2017-08-02

Eric Kumpa  
Manager QA/RA

Dr. Boris Behnisch  
Business Development

[Vers.2014/01]

This document has to be maintained at least five years after the last production of the concerned product was achieved.

*Bertifikat - Certificate - Certificat*





Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## EC Design-Examination Certificate No. 17 0354 CN/NB

issued for manufacturer

**Translumina GmbH**

Neue Rottenburger Strasse 50, 72379 Hechingen, Germany

in accordance with requirements of

**Directive 93/42/EEC**

**on medical devices, Annex II (4)**

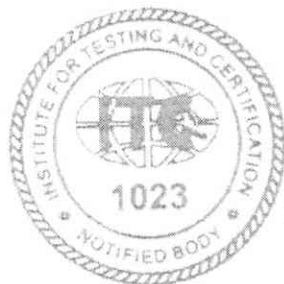
for the following product category(ies):

**Sirolimus Eluting Coronary Stent System**

The Notified Body No. 1023 has performed an examination of the design dossier relating to devices / device categories in accordance with MDD Annex II. The design of the devices conforms to the requirements of this Directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

Valid from: 2017-07-31  
Valid until: 2022-07-30  
First Issued: 2017-07-31  
Revision: -

Date: 2017-07-31



*Paul*  
RNDr. Radomír Čevelík  
Representative of the Notified Body No. 1023





Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 17 0353 QS/NB  
issued for manufacturer:

**Translumina GmbH**  
**Neue Rottenburger Strasse 50, 72379 Hechingen, Germany**

**Facility(ies):**

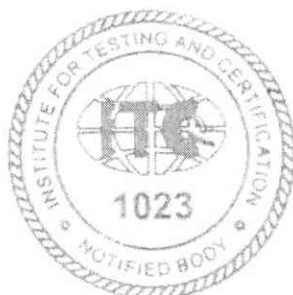
Translumina GmbH

Address:

Neue Rottenburger Strasse 50, 72379 Hechingen, Germany

Lotzenaecker 11, 72379, Hechingen, Germany

Lotzenaecker 3, 72379 Hechingen, Germany



Date: 2017-07-31  
Revision: -

*Radomir Čevelík*  
RNDr. Radomír Čevelík  
Representative of the Notified Body No. 1023



Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

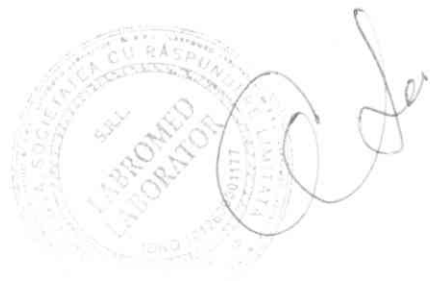
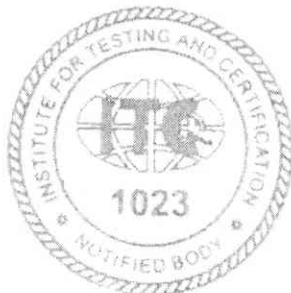
**Annex to EC Certificate No. 17 0353 QS/NB**  
issued for manufacturer:

**Translumina GmbH**  
**Neue Rottenburger Strasse 50, 72379 Hechingen, Germany**

**Certificate History:**

Revision	Date	Reference Number	Action
	2017-07-31	803602400	Certification

Date: 2017-07-31  
Revision: -



*R. Radomir Čevčík*  
RNDr. Radomír Čevčík  
Representative of the Notified Body No. 1023



Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## Annex to EC Design-Examination Certificate

No. 17 0355 CN/NB

issued for manufacturer:

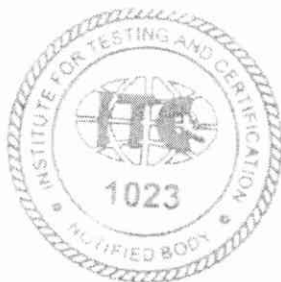
**Translumina GmbH**  
**Neue Rottenburger Strasse 50, 72379 Hechingen, Germany**

### Product:

**Name:** Sirolimus Eluting Coronary Stent System  
**Trade name(s):** Yukon® Chrome PC  
**Model(s):** SV small vessel version (2,0-2,5mm)  
MV medium vessel version (2,75-4,0mm)  
See below the reference numbers  
**Class:** III  
**GMDN:** 58771

Stamp: SOCIETATEA CU RASPUNDABILITATE  
SRL  
LABORATOR  
INSTITUTUL NATIONAL DE METROLOGIE SI TESTARE  
1023

Date: 2017-07-31  
Revision:-



**RNDr. Radomír Čevelík**  
Representative of the Notified Body No. 1023



Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
trída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## Annex to EC Design-Examination Certificate

### No. 17 0355 CN/NB

issued for manufacturer:

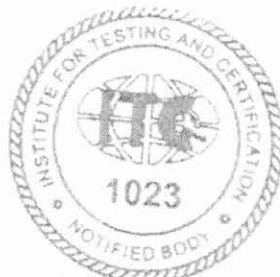
**Translumina GmbH**  
**Neue Rottenburger Strasse 50, 72379 Hechingen, Germany**

#### Reference numbers:

T-CMG2008PC	T-CMG22508PC	T-CMG2508PC	T-CMG27508PC	T-CMG3008PC	T-CMG3508PC	T-CMG4008PC
T-CMG2012PC	T-CMG22512PC	T-CMG2512PC	T-CMG27512PC	T-CMG3012PC	T-CMG3512PC	T-CMG4012PC
T-CMG2016PC	T-CMG22516PC	T-CMG2516PC	T-CMG27516PC	T-CMG3016PC	T-CMG3516PC	T-CMG4016PC
T-CMG2018PC	T-CMG22518PC	T-CMG2518PC	T-CMG27518PC	T-CMG3018PC	T-CMG3518PC	T-CMG4018PC
T-CMG2021PC	T-CMG22521PC	T-CMG2521PC	T-CMG27521PC	T-CMG3021PC	T-CMG3521PC	T-CMG4021PC
T-CMG2024PC	T-CMG22524PC	T-CMG2524PC	T-CMG27524PC	T-CMG3024PC	T-CMG3524PC	T-CMG4024PC
T-CMG2028PC	T-CMG22528PC	T-CMG2528PC	T-CMG27528PC	T-CMG3028PC	T-CMG3528PC	T-CMG4028PC
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			T-CMG27540PC	T-CMG3040PC	T-CMG3540PC	T-CMG4040PC



Date: 2017-07-31  
Revision:-



*R. Radomir Čevelík*  
RNDr. Radomír Čevelík  
Representative of the Notified Body No. 1023





Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## Annex to EC Design-Examination Certificate

### No. 17 0355 CN/NB

issued for manufacturer:

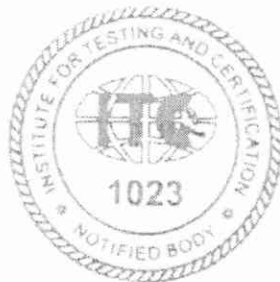
**Translumina GmbH**  
**Neue Rottenburger Strasse 50, 72379 Hechingen, Germany**

#### Certificate History:

Revision	Date	Reference Number	Action
	2017-07-31	803602400	Certification



Date: 2017-07-31  
Revision: -



*Radomir Čevelík*  
RNDr. Radomír Čevelík  
Representative of the Notified Body No. 1023



Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## Annex to EC Design-Examination Certificate

### No. 17 0354 CN/NB

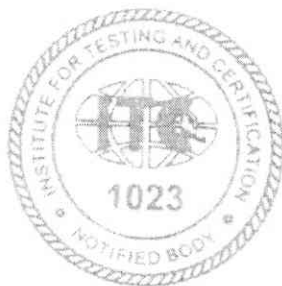
issued for manufacturer:

**Translumina GmbH**  
**Neue Rottenburger Strasse 50, 72379 Hechingen, Germany**

#### Product:

**Name:** **Sirolimus Eluting Coronary Stent System**  
**Trade name(s):** Yukon® Choice PC  
**Model(s):** SV small vessel version (2,0-2,5mm)  
MV medium vessel version (2,75-4,0mm)  
See below the reference numbers  
**Class:** III  
**GMDN:** 58771

Date: 2017-07-31  
Revision:-



  
RNDr. Radomir Čevelík  
Representative of the Notified Body No. 1023





Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
trída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## Annex to EC Design-Examination Certificate

### No. 17 0354 CN/NB

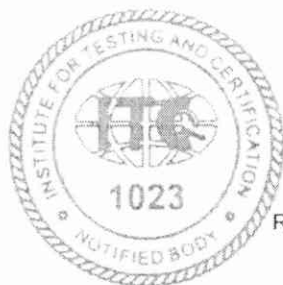
issued for manufacturer:

**Translumina GmbH**  
**Neue Rottenburger Strasse 50, 72379 Hechingen, Germany**

#### Reference numbers:

YCPC2008	YCPC2208	YCPC2508	YCPC2708	YCPC3008	YCPC3508	YCPC4008
YCPC2012	YCPC2212	YCPC2512	YCPC2712	YCPC3012	YCPC3512	YCPC4012
YCPC2016	YCPC2216	YCPC2516	YCPC2716	YCPC3016	YCPC3516	YCPC4016
YCPC2018	YCPC2218	YCPC2518	YCPC2718	YCPC3018	YCPC3518	YCPC4018
YCPC2021	YCPC2221	YCPC2521	YCPC2721	YCPC3021	YCPC3521	YCPC4021
YCPC2024	YCPC2224	YCPC2524	YCPC2724	YCPC3024	YCPC3524	YCPC4024
YCPC2028	YCPC2228	YCPC2528	YCPC2728	YCPC3028	YCPC3528	YCPC4028
YCPC2032	YCPC2232	YCPC2532	YCPC2732	YCPC3032	YCPC3532	YCPC4032
-	-	-	YCPC2740	YCPC3040	YCPC3540	YCPC4040

Date: 2017-07-31  
Revision: -



  
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Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## Annex to EC Design-Examination Certificate

### No. 17 0354 CN/NB

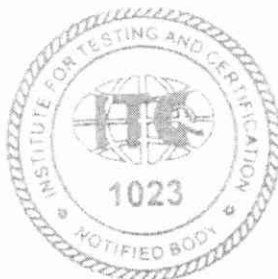
issued for manufacturer:

**Translumina GmbH**  
**Neue Rottenburger Strasse 50, 72379 Hechingen, Germany**

#### Certificate History:

Revision	Date	Reference Number	Action
	2017-07-31	803602400	Certification

Date: 2017-07-31  
Revision:-



*Radomir Čevelík*  
RNDr. Radomír Čevelík  
Representative of the Notified Body No. 1023

translumina GmbH  
Neue Rottenburger Straße 50  
72379 Hechingen  
Germany

Your ref.  
Our ref. 2222713-TCP-R1  
Tel. +31 88 96 83 009  
Fax +31 88 96 83 100  
E-mail [medical.nl@dekra.com](mailto:medical.nl@dekra.com)

Arnhem, 27 February 2018

Subject:  
Certification status

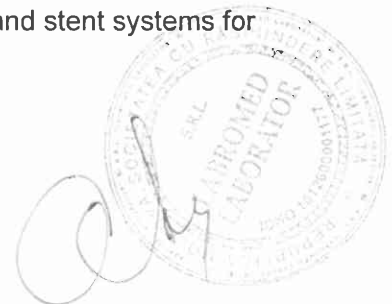
To Whom It May Concern,

DEKRA Certification, in its capacity of Notified Body for Medical Devices, declares, based on the results of the inspection and assessment activities performed, in reference to the Technical Cooperation Programme on Exchange of Medical Device GMP and ISO 13485 Audit Reports between EU AIMD/MDD/IVDD Notified Body Partners and R.O.C. TFDA Authorized Medical Device GMP Auditing Organizations (TCP), the following:

The most recent audit DEKRA Certification Notified Body performed at translumina GmbH facilities was performed on 28-30 November 2018. The scope of the audit was Certification audit TCP Audit in accordance with Clients QMS and ISO 13485:2003 (RvA accredited) / R.O.C. TCP program. The results of the assessment are documented in 2222713-AR01-R1, issued on 27 February 2018.

The ISO certificate 2222713 bears the following scope:

Design, development, manufacturing and distribution of catheters and stent systems for cardiology and radiology



It covers the following products sold by translumina GmbH in R.O.C., through:

Hsin Tung Medical Co., Ltd.  
7F., No. 180, Sec. 6  
Zhongxiao E. Rd., Nangang Dist.  
Taipei City 115  
Taiwan

Product Group: Coronary Stent

Yukon® CC (bare metal stent, CoCr)  
Yukon® Choice 4 (bare metal stent, stainless steel thin struts)

Product Group: PTCA Catheters

Cathy No. 4

The DEKRA Certification B.V. approved production location:

translumina GmbH  
Neue Rottenburger Straße 50  
72379 Hechingen  
Germany

The above referenced documents are all valid documents, issued by DEKRA Certification Notified Body.

With kind regards,  
DEKRA Certification B.V.



ing. A.A.M. Laan  
Certification Manager Medical Devices



# CERTIFICATE

Number: 2222713

The management system of:

**translumina GmbH**

Neue Rottenburger Straße 50  
72379 Hechingen  
Germany

including the implementation meets the requirements of the standard:

## ISO 13485:2003

Scope:

Design, development, manufacturing and distribution of catheters and stent systems for cardiology and radiology.

Certificate expiry date: 1 March 2019  
Certificate effective date: 7 February 2018  
Certified since: 7 February 2018

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

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